DOCKET NO: 213445US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
HIROAKI NAKAGAMI, ET AL.	: EXAMINER: PULLIAM, A.
SERIAL NO: 09/926,123	:
FILED: SEPTEMBER 6, 2001	: GROUP ART UNIT: 1615
FOR: PHARMACEUTICAL COMPOSITION	:

DECLARATION UNDER 37 C.F.R. §1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

I, _____, the undersigned, a citizen of _____, one of the applicants of the above-captioned U.S. Patent Application No. 09/926,123, do hereby declare:

1. That I am a graduate of_____ and received my _____ degree in the year ____.

2. That I have been employed by _____ _____for ___ years as a _____ in the field of _____.

3. That the following comparisons and comparisons referred to in the specification was carried out by me or under my direct supervision and control.

4. That I am familiar with the present application, its prosecution history, and the outstanding rejections over the cited references.

5. That I am familiar with the pending claims in the present application.

6. That I hereby state that the following remarks regarding procedure, result generation, and data interpretation is done so to the best of my knowledge in the related technical field and that I have read and understand all information herein.

7. In view of the Examiner's position shown in the Office Action mailed May 21, 2003, in order to demonstrate the patentability of the claimed methods, products, and compositions.

The enclosed test data demonstrate that the particle size ranging from 50-200 μm of the granule is able to bring substantial improvement to the qualities of the claimed composition, i.e., by enhancing favorable sensation and preventing the throat from irritation. I believe that the enclosed data is demonstrates that the claimed composition having sand particle laze ranging from 50-200 μm is superior to compositions failing to be adjusted to said range.

Meanwhile, it can be deduced from Table 2 of the present specification as originally filed that the claimed granule composition can flow through a tube having a diameter of at most 1 mm without clogging the tube. By this table, the secondary granule proved to be able to flow through said tube without the clogging. Therefore, the primary granule having a particle size ranging from 50-200 μm can more easily flow through said tube without any clogging. Thus I am of the opinion that said ability is already evident from the existing data of the present specification.

Even in spite of the above, I believe that the enclosed data "Supplemental Examples" and the above comments are sufficient to clarify the Examiner's questions regarding patentability.

Supplemental Examples

A comparative test was performed using granular compositions prepared according to the following, in order to investigate whether there are any significant differences depending on, their particle sizes.

Supplemental Example 1

Glycerin monostearate (230 parts by weight) was melted at 90°C, and polyoxyethylene (20) sorbitan monostearate (polysorbate 80) (3 parts by weight) was added thereto. Ticlopidine hydrochloride (100 parts by weight) was uniformly dispersed in the resultant mixture. The dispersion was spray-cooled by use of a spray drier to thereby obtain minute granules.

Supplemental Example 2

Glycerin monostearate (225 parts by weight) was melted at 95°C, and polyoxyethylene (20) sorbitan monostearate (polysorbate 80) (3 parts by weight) was added thereto. Ticlopidine hydrochloride (100 parts by weight) was uniformly dispersed in the resultant mixture. The dispersion was spray-cooled by use of a spray drier to thereby obtain minute granules.

Test methods

1) Favorable sensation:

Each of the granules was put in the mouth, and favorable sensation was tested while said granule was held in the mouth for a period of 30 seconds. The favorable sensation was evaluated on the following criteria.

A: No perceivable roughness was manifested.

B: Roughness was slightly perceived, but was tolerable.

C: Roughness was perceived.

2) Irritation of the throat:

Each of the granules was punt in the mouth, and the irritation of the throat was tested while said granule was held in the mouth for a period of 30 seconds. The irritation of the throat was evaluated on the following criteria.

A: No perceivable irritation was manifested.

B: Irritation was slightly perceived.

C: Irritation was perceived.

The results are shown in the following tables.

Table 1

Particle sizes (μm)	Favorable sensation	
	Supplemental Example 1	Supplemental Example 2
> 250	C	C
150-250	C	C
125-150	B	B
110-125	A	A
75-110	A	A
50-75	A	A
<50	A	A

Table 2

Particle sizes (μm)	Irritation of the throat	
	Supplemental Example 1	Supplemental Example 2
> 250	A	A
150-250	A	A
125-150	A	A
110-125	A	A
75-110	A	A
50-75	B	B
<50	B	C

Results

Table 1 shows that favorable sensation is not satisfied when the particle size of the granules exceeds a range of 150-250 μm. Meanwhile, Table 2 shows that the granules could cause irritation to the throat when the particle size is less than 50 μm. Taken together, it is considered that the claimed composition having the particle size ranging from 50 to 200 μm is superior to compositions not falling within such a range.

8. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

9. Further deponent saith not.

_____

Signature

_____

Date